K112441

510(K) SUMMARY

[as required by 807.92(c)]

JAN 17 2012

A. 510k Number:

B. Applicant:

Company name: PATS CORP
Address: 205 S Broadway, Suite 718, Los Angeles California 90012 USA
Contact person: Daniel Nam
Phone: 213-626-1544

C. Proprietary and Established Names: DAESUNG MAREF CO LTD

Address: 689-31 Gumjung-dong, Gunpo-si Gyeonggi-do 451-864 KOREA

D. Regulatory Information

1. Classification Name: Massager, Powered Inflatable Tube
2. Common / Usual Name: Powered Inflatable Tube Massager
3. Proprietary Name: Compressible Limb Therapy System MK300L
4. Classification / Product Code: Class II / IRP (21 CFR 890.5650)

E. Intended Use

MK300L is intended for use by medical professionals and patients at home, who are under medical supervision, in treating many conditions, such as : Primary lymphedema, Edema following trauma and sport injuries, Postimmobilization edema, Venous insufficiencies, Lymphedema.

F. Device Description

MK300L is used with four chamber garments for full leg, and period has its own variable duration,pressure, cycle time and gradient setting. Power unit features visual operation statusand fault indicators.

G. Substantial Equivalence Information

1. Predicate Device

Predicate Device 1
- 510(k) number: K013331
- Name: Lympha press plus
- Classification: 2

Predicate Device 2
- 510(k) number: K012320
- Name: LX-7
- Classification: 2

Predicate Device 3
- 510(k) number: K102319
- Name: WIC-2008

- Classification: 2

2. Comparison with predicate
Compressible Limb Therapy System MK300L has substantial equivalent intended use as the-market-cleared LX-7 and has substantial equivalent technological and performance characteristics with Lympha press plus and WIC-2008.After analyzing both bench as well as laboratory testing to applicable standards, it is the conclusion of Compressible Limb Therapy System MK300L is as safe and effective as the predicate devices, has few technological differences, but there are no new indications for use and without raising any new safety and/or effectiveness concerns.
Consequently, it is clear that it substantially equivalent to the predicate devices.

H. Performance Characteristics (If/when applicable)
MK300L has conducted and applied by standard of

- Council Directive 93/42/EEC of 14 June 1993 concerning medical devices
- IEC 980:2003, Graphical symbols for use in the labeling of medical devices
- IEC1041:1998, Information supplied by the manufacturer with medical devices
- ISO 13485:2003, Medical devices - Quality management systems - Requirements for regulatory purposes
- ISO 14155-1:2003, Clinical investigation of medical devices for human subjects - Part 1: General requirements
- ISO 14971:2007, Medical devices - Application of risk management to medical devices
- IEC 60601-1, Medical electrical equipment - Part 1: General requirements for safety (IEC 60601-1:1988/A1:91/A2:95)
- IEC 60601-1-2, Medical electrical equipment - Part 1: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Daesung Maref Co. Ltd.
% PATS Corporation
Mr. Daniel Nam
205 South Broadway, Suite 718
Los Angeles, California 90012

JAN 17 2012

Re: K112441
Trade/Device Name: Compressible Limb Therapy System MK300L
Regulation Number: 21 CFR 890.5650
Regulation Name: Powered inflatable tube massager
Regulatory Class: Class II
Product Code IRP
Dated: December 5, 2011
Received: December 9, 2011

Dear Mr. Nam:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

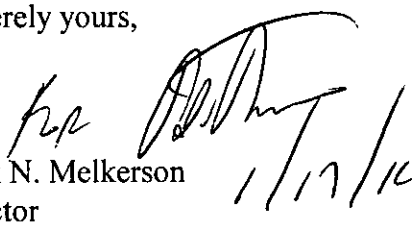
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Indications for Use

510(k) Number (if known):

Device Name: Compressible Limb Therapy System MK300L

Indications For Use: MK300L is intended for use by medical professionals and patients at home, who are under medical supervision, in treating many conditions, such as : Primary lymphedema, Edema following trauma and sport injuries, Postimmobilization edema, Venous insufficiencies, Lymphedema.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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